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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,218	12/21/2001	Patrick L. Coleman	54913US111	2257

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/20/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/027,218

Applicant(s)

COLEMAN ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13,14 and 17 is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,15,16 and 18-23 is/are rejected.
- 7) ☒ Claim(s) 8 and 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This is a CIP of 09/589,580, filed on 06-07-2000, now US 6,451,810. Claims 1-23 are pending.

The specification has been amended to cross reference to the above parent application, and provisional application of 60/138,365.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of **inducing biosynthesis of INF- α (interferon- α), and TNF- α (tumor necrosis factor- α)**, does **not** reasonably provide enablement **for the method** of inducing biosynthesis of **other cytokines** such as various interleukins, and other INF's as well as other TNF's. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;

- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

On page 151, the specification lists the lowest effective concentration that the claimed compounds can induce the biosynthesis of INF- α and TNF- α . Said data cannot be extrapolated to the induction of biosynthesis of other cytokines because they have different biosynthesis pathways and/or produced by different cells. Although the specification asserts that the claimed compounds have an effect on T cells, and cause proliferation and differentiation of B-lymphocytes, said compounds have not been tested for either effect. Therefore, there is insufficient guidance for the skilled scientist to apply the claimed compounds in inducing biosynthesis of other cytokines such as various IL's, other INF's, or TNF's.

The state of the art, as evident by *Nanba et. al.* (US'149), only relates analogous compounds to the induction of INF (α , γ). Furthermore, said teaching applies analogous compounds in the treatment of inflammatory diseases, and not cancers or viral infections. Thus, one skilled in the art cannot rely on the teaching of *Nanba et. al.* to remedy the enablement deficiency of the instant disclosure.

Thus, given the broad scope of the claims, the unpredictable nature of the art, and limited guidance, the skilled scientist will have to carry out undue experimentation to use the claimed compounds in inducing biosynthesis of other cytokines.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-3, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by **Nanba et. al.** (US 6,069,149). Nanba et. al. disclose many compounds (e.g., see compounds of Examples 40-48, 51, 55, 56, etc.) that are embraced by the instant formula (I) with the following substituents:

- i. R_1 is C_4 -alkyl- NR_3 -CO- R_4 ;
- ii. R_3 is hydrogen, and R_4 is substituted aryl;
- iii. R_2 is hydrogen;
- iv. $n = 0$, or R does not exist.

Said compounds also induce $INF-\alpha$. Thus, their composition, and method of use also read on the those claimed herein.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3-7, 9-11, 15, 16, 18, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, 20-23, 29-32, 43-45, 48 of U.S. Patent No. 6,451,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following overlapping subject matter:

- a. The composition of formula (I) in claims 1-3 of US'810 read on that of formula (I) in the instant claims 1, and 3, particularly when R_1 of US'810 represents $-\text{alkyl}-\text{NR}_3-\text{CO}-\text{R}_4$.
- b. The composition of formula (Ib) in claim 8 of US'810 reads on that of formula (Ib) in the instant claim 4, particularly, when R_1 of US'810 represents $-\text{alkyl}-\text{NR}_3-\text{CO}-\text{R}_4$ with R_4 as a heterocyclyl group.
- c. The compounds of formula (Id) in claims 20-23 of US'810 embrace those of formula (Id) in the instant claims 5-7, particularly, when R_1 of US'810 represents $-\text{alkyl}-\text{NR}_3-\text{CO}-\text{R}_4$ with R_4 as a heteroaryl group.
- d. The compounds of formula (Ie) in claims 29-32 of US'810 embrace those of formula (Ie) in the instant claims 9-11, particularly, when R_1 of US'810 represents $-\text{alkyl}-\text{NR}_3-\text{CO}-\text{R}_4$ with R_4 as an alkyl group.
- e. The composition in claim 43 of US'810 is similar to that of the instant claim 15 since both claims refer to the same formula (Id).
- f. The composition in claim 44 of US'810 is similar to that of the instant claim 16 since both claims refer to the same formula (Ie).
- g. The method in claim 45 of US'810 is similar to that of the instant claim 18 since both refer to the same formula (I).
- h. The method in claim 48 of US'810 is similar to that of the instant claim 19 since both refer to the same formula (Ib).

Claim Objections

4. Claims 8 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

5. Claims 13, 14, and 17 are allowable since the prior arts of record do not teach species and their composition as claimed herein.

Information Disclosure Statement

The IDS of 6-16-02 and 9-13-02 have been considered.

On the IDS of 6-16-02, the entry of **Baranov et. al.** appears to have the wrong abstract number. Applicant is advised to clarify the citation of said entry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Tamthom N. Truong
Examiner
Art Unit 1624



May 17, 2003